DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Purged 8/22/97 HFI-35

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

571

August 20, 1997

WARNING LETTER

RETURN RECEIPT REQUESTED
VIA CERTIFIED MAIL

NWE-12-97

Ms. April M. Mason, President
Lifeplus, Inc.
Ten Lane Road
P. O. Box 1500
Raymond, NH 03077-1500

Dear Ms. Mason:

During an inspection of Lifeplus, Inc., Falmouth, Maine conducted on July 16 and 17, 1997 our Investigator determined that your firm manufactures liquid medical oxygen. This medical gas is a drug as defined by section 210(g) of the Federal Food, Drug and Cosmetic Act (the Act). The inspection revealed that this drug is adulterated under section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for, its manufacturing, packing, holding, or shipping are not in conformance with the Current Good Manufacturing Practice Regulations for drugs specified in Title 21, Code of Federal Regulations, (CFR), Parts 210 and 211, as follows:

1. Failure to conduct complete USP testing of each shipment of liquid oxygen in cryogenic containers (received without a valid certificate of analysis), prior to its transfilling into other cryogenic units. Because your firm neither witnesses the testing of the liquid oxygen, nor receives a valid certificate of analysis, you are required to conduct complete USP testing. Testing of home cryogenic units is not required as long as the incoming liquid oxygen is adequately tested.

2. Failure to document each significant step in the calibration of the oxygen identity test equipment, the [redacted]

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your firm. We mailed you a copy of the FD483, Inspectional Observations, with cover letter dated July 18, 1997. We also sent you the Inspectional Report with cover letter dated July 28, 1997. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice Regulations and this responsibility encompasses all locations . Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

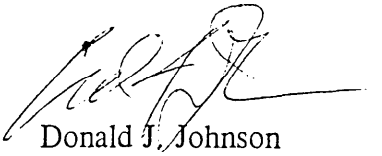
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter regarding the specific steps you have taken to prevent a recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, please state the reason for the delay and the time within which corrections will be implemented.

Your written response should be directed to E. Frank Gesing, Compliance Officer, U. S. Food and Drug Administration, One Montvale Avenue, Stoneham, MA 02180.

If you have any questions concerning this matter, please contact Mr. Gesing at (617) 279-1675 extension 127.

Sincerely,



Donald J. Johnson
Acting District Director
New England District Office

cc: Sally M. Powers
Regional Manager
Lifeplus, Inc.
43 US Route 1
Falmouth, ME 04105